HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

9/910d

Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL – 10389-02
October 4, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dennis Justice.
Senior Physicist
The Toledo Hospital – Promedica West
3740 Sylvania Ave.
Toledo, OH 43623

Facility I.D.#: 156588

Dear Mr. Justice:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on September 18, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following **repeat** Level 2 finding at your facility:

Quality Assurance - Equipment— 21 CFR 900.12(e)(4)(ii)

The measured darkroom fog density was found to be 0.22. The regulation requires the optical density attributable to darkroom fog shall not exceed 0.05.

The inspector conducted a darkroom fog test using an approved mammography phantom and your facility film system. The phantom film was placed in a fog folder and exposed to your facility typical darkroom conditions with the safelights for two minutes. When the two minutes lapsed, the film was processed on your facility processor. The processed phantom film was measured for differences in optical density between the fogged and unfogged portion.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. The problem is identified as **repeat** Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement **permanent correction** of the problem found during all of your previous annual inspections, since 1996.

In addition, your response should address the Level 2 and Level 3 repeat findings that are listed in the inspection report that was provided to you. These findings are:

Level 2 Findings:

1. **Personnel- Interpreting Physicians - *21* CFR 900.12 (a)(1)(ii)(B)**
   Your facility failed to produce documents demonstrating that [redacted], an interpreting physician meets the requirement of having taught or completed a minimum of fifteen (15) category 1 continuing education units in mammography in thirty six (36) months.

2. **Quality Assurance – *Mammography Medical Outcomes Audit* 21 CFR 900.12(f)(1)& (2)**
   Your staff failed to show that an annual medical audit and outcomes analysis was performed individually and collectively for all interpreting physicians at your facility only.

Level 3 *Repeat* Finding:

Retention of Personnel Records - 21 CFR 900.12 (a)(4)
During the inspection at your facility and upon request by the inspector, your staff was unable to provide the required personnel qualification documentation for review by the inspector.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received. The problem is identified as **repeat Level 3** because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent correction of the problem found during your previous inspection on September 21, 2000.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

The other items listed in your September 20, 2001 inspection report identified, as Level 3 should also be corrected. We will verify corrections on these items during our next inspection. You are not required to address the Level 3 items in your written response.

It is necessary for you to act on these matters immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter; and
- Each step your facility is taking **to prevent the recurrence** of similar violations.

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Also, please send a copy to the State radiation control office:

Ms. Cindy Grant
Ohio Department of Health
1 Government Center
Suite 1320
Toledo, OH 43604

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at through the Internet at http://www.fda.gov/cdrh/mammography.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

Henry L. Fielden
District Director
Cincinnati District Office

c.
OH/CGrant

Priscilla F. Butler, M.S.
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American College of Radiology
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